

OCT 22 2003

K032714

510(K) SUMMARY- CARDICARE MODEL MT-301F & MT-301C THERMOMETER

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92

Priority Name: Cardicare Model MT-301F & MT-301C
Common/ Usual Name: Digital Electronic Thermometer
Classification Name: Clinical Electronic Thermometer (per 21 CFR 880.2910)
Legally Marketed Device: Jasun, Model DT-01F, Hangzhou Hua'an Medical & Health Instruments Company.

Device Description: The Cardicare Model MT-301F & MT-301C Thermometers are thermometers of standard electrical transducer design, consisting of a sensor tip, connecting probe and display unit. The probe consists of a transducer and supporting plastic case, which houses the connection between the sensor and the circuitry. The display unit houses a 1.55V DC button battery, LCD and push button switch for controlling temperature and alert beeper.

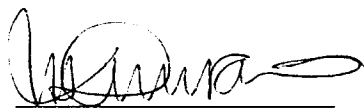
Intended Use: The Cardicare MT-301F & MT-301C Thermometers have the same intended use as the predicate device. It is indicated for use in the measurement of oral, axillary and rectal temperature. The MT-301F & MT 301C Thermometers are intended for home use by the patient.

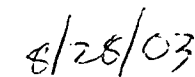
Technological Characteristic: The Cardicare MT-301F & MT301-C Thermometers have the same technological features as the predicate device: The mode of operation, physical specifications, operational and biological specifications are identical.

Performance Data: QC Lab by Sejoy Electronics testing, China, performed on the Cardicare MT-301F & MT-301C Thermometers confirmed accuracy, precision and repeatability measurements specified in labeling.

Substantial Equivalence: The information provided demonstrates that the Cardicare MT-301F & MT-301C Thermometers are substantially equivalent to the predicate device since the devices have the same intended use, principles of operation and technological characteristics.

Contact Person:


Mario D. Manzano


Date Prepared



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 2003

Ms. Mario Manzano
Director, Quality Assurance
Lumiscop Company, Incorporated
122 Tices Lane
East Brunswick, New Jersey 08816

Re: K032714

Trade/Device Name: Digital Fever Thermometer, Oral, Rectal and Axillary
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: October 13, 2003
Received: October 16, 2003

Dear Mr. Manzano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

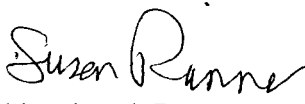
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


Chiu Lin, Ph.D.

Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032714

Device Name: Digital Fever Thermometer, Oral, Rectal and Axillary

Indication For Use:

The Cardicare Model MT-301C and Model MT-301F digital thermometers are intended for use in the measurement of oral, axillary and rectal body temperature.

Paloma Cucente

(Division Sign-Off)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K 032714

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)